

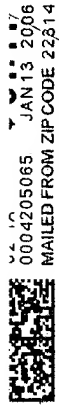
P.O. BOX 1450

ALEXANDRIA, VA 22313-1450

IF UNDELIVERABLE RETURN IN TEN DAYS

OFFICIAL BUSINESS

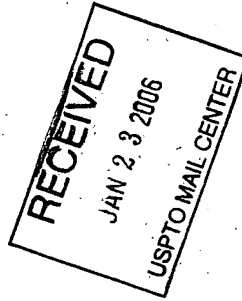
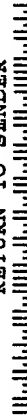
AN EQUAL OPPORTUNITY EMPLOYER



0004205065 JAN 13 2006
MAILED FROM ZIP CODE 22314

KOS-001 331310398 1B04 20 01/18/06
FORWARD TIME EXP RTN TO SEND
:KOS PHARMACEUTICALS
2200 N COMMERCE PKWY STE 300
WESTON FL 33326-3258

RETURN TO SENDER





UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 01/13/2006
Karen J Messick ESQ
c/o KOS Pharmaceuticals Inc
1001 Brickell Bay Drive
25th Floor
Miami, FL 33131



EXAMINER	
CHANNAVAJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1615	
DATE MAILED: 01/13/2006	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	32892-00023	6174

TITLE OF INVENTION: METHODS FOR TREATING HYPERLIPIDEMIA WITH INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$0	\$700	04/13/2006

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail**

**Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
(571) 273-2885**

or **Fax**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

7590

01/13/2006

**Karen J Messick ESQ
c/o KOS Pharmaceuticals Inc
1001 Brickell Bay Drive
25th Floor
Miami, FL 33131**

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	32892-00023	6174

TITLE OF INVENTION: METHODS FOR TREATING HYPERLIPIDEMIA WITH INTERMEDIATE RELEASE NICOTINIC ACID COMPOSITIONS HAVING UNIQUE BIOPHARMACEUTICAL CHARACTERISTICS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$0	\$700	04/13/2006

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHANNAVAJALA, LAKSHMI SARADA	1615	424-468000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list
 (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
 1 _____
 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

- ☐ A check in the amount of the fee(s) is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	32892-00023	6174

7590 01/13/2006

Karen J Messick ESQ
c/o KOS Pharmaceuticals Inc
1001 Brickell Bay Drive
25th Floor
Miami, FL 33131

EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 01/13/2006

Determination of Patent Term Extension under 35 U.S.C. 154 (b) (application filed after June 7, 1995 but prior to May 29, 2000)

The Patent Term Extension is 0 day(s). Any patent to issue from the above-identified application will include an indication of the 0 day extension on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Extension is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Notice of Allowability

Application No.

08/960,557

Examiner

Lakshmi S. Channavajjala

Applicant(s)

CEFALI ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4-5-05, 4-27-05, 1-4-05, 1-11-05.
2. ☒ The allowed claim(s) is/are 29, 30, 32-36, 38-42 and 44-61.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1-4-05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Examiner's Amendment

The application has been amended as follows:

On the page titled "Listing of claims", before claim 29, insert:

1-28. Cancelled.

Art Unit: 1615

Allowable Subject Matter

Claims 29, 30, 32-36, 38-42, 44-61 are allowed.

The following is an examiner's statement of reasons for allowance:

Instant claims are directed to a method of treating cholesterol disorders with an immediate release nicotinic acid, wherein the formulation have a dissolution curve similarity of fit factor F2 of at least 44 and have specific release characteristics at different time intervals. While nicotinic acid treatment for controlling cholesterol disorders is known, absent the instant disclosure the intermediate release of nicotinic acid for up to 20 hours would not have been obvious for one of an ordinary skill in the art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
January 5, 2006

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

The drawings submitted with this application were declared informal by the applicant. Accordingly they have not been reviewed by a draftsperson at this time. When formal drawings are submitted, the draftsperson will perform a review.

Direct any inquires concerning drawing review to the Drawing Review Branch (703) 305-8404.

Substitute PTO-948

BEST AVAILABLE COPY

FORM PTO 1449 (modified)				ATTY DOCKET NO. 5045-56103USCIP		APPLICATION NO. 08/960,577	
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)				APPLICANT Eugenio Cefali, et al.			
				FILING DATE 31 October 1997			GROUP 1615
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO/ OR ABSTRACT
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)							
DOCUMENTS SUBMITTED UNDER MPEP § 724							
RECEIVED JAN 04 2005 OFFICE OF PETITIONS							
		Expert Report of Cheryl D. Blume, Ph.D. (January 27, 2004) - Subject to Protective Order					
		Expert Report of Dr. Sergio Fazio (February 4, 2004) [Redacted Version] - Subject to Protective Order					
		Rebuttal Expert Report of Dr. Sergio Fazio (April 2, 2004) - Subject to Protective Order					
		Expert Report of Dr. Sergio Fazio Regarding U.S. Patent No. 6,676,967 (August 17, 2004) - Subject to Protective Order					
		Expert Report of Don W. Martens (February 6, 2004) [Redacted Version] - Subject to Protective Order					
		Expert Report of Don W. Martens Regarding U.S. Patent No. 6,676,967 (August 20, 2004) [Redacted Version] - Subject to Protective Order					
		Expert Report of Dr. Joseph R. Robinson (February 5, 2004) [Redacted Version] - Subject to Protective Order					
		Expert Report of Dr. Joseph R. Robinson Regarding U.S. Patent No. 6,676,967 (August 18, 2004) - Subject to Protective Order					
EXAMINER		L. Channavajjala			DATE CONSIDERED		
					12/29/05		


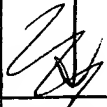
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)	ATTY DOCKET NO.	APPLICATION NO.
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	5045-56103USCIP	08/980,577
	APPLICANT Eugenio Cefali, et al.	
	FILING DATE 31 October 1997	GROUP
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)	RECEIVED JAN 04 2005 OFFICE OF PETITIONS	1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)		
DOCUMENTS SUBMITTED UNDER MPEP § 724		
	Rebuttal Expert Report of Thomas S. Foster, Pharm.D. (April 2, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Thomas S. Foster, Pharm.D. Regarding The '967 Patent (October 4, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of James W. McGinity, Ph.D. (April 2, 2004) - Subject to Protective Order	
	Supplemental Rebuttal Expert Report of James W. McGinity, Ph.D. (August 18, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of James W. McGinity, Ph.D. Regarding The '967 Patent (September 30, 2004) - Subject to Protective Order	
	Expert Report of Mark E. McGovern, M.D. (February 6, 2004) - Subject to Protective Order	
	Expert Report of Mark E. McGovern, M.D. (August 20, 2004) - Subject to Protective Order	
	Expert Report of Frank M. Sacks, M.D. (April 2, 2004) - Subject to Protective Order	
	Expert Report of Frank M. Sacks, M.D. (August 20, 2004) - Subject to Protective Order	
	Rebuttal Expert Report of Mary Ann Tucker, Esq. (April 2, 2004) - Subject to Protective Order	
Rebuttal Expert Report of Mary Ann Tucker, Esq. Regarding The '967 Patent (October 1, 2004) - Subject to Protective Order		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.

L. Channarayana

12/29/05

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/880,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		APPLICANT Eugenio Cefali, et al.	
		FILING DATE 31 October 1997	GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
DOCUMENTS SUBMITTED UNDER MPEP § 724			
		Sample Kos Clinical Trial Medical Consent Form - Subject to Protective Order	
		Sample Kos Clinical Trial Investigator's Statement - Subject to Protective Order	
EXAMINER	<i>L. Channarayana</i>		DATE CONSIDERED <i>12/29/05</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)	ATTY DOCKET NO. 5045-56103USCIP APPLICANT Eugenio Cefali, et al.	APPLICATION NO. 08/880,577 <div style="text-align: center; font-size: 1.5em; font-weight: bold;">RECEIVED</div> <div style="text-align: center;">JAN 04 2005</div> <div style="text-align: center; font-weight: bold;">OFFICE OF PETITIONS</div>
		GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Carl J. Lavie, et al., <i>Marked Benefit with Sustained-Release Niacin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease</i>, Am. J. Cardiol. 1992:69:1083-1085
		Excerpts from the 1993, 2000 and 2002 editions of the Physician's Desk Reference 1993 edition (pp. 434, 611, 856, 1189, 1919, 1920, 2491 and 2492) 2000 edition (pp. 1519-1523) 2002 edition (pp. 1846-1850)
		<i>Niacin: Double-edged Sword for Lowering Cholesterol</i>, Tufts University Diet & Nutritional Letter (Tufts Univ., Boston, MA), August 1994, Vol. 12, issue 6
		Larsen, ML and Illingworth, DR, <i>Drug Treatment of Dyslipoproteinemia</i>, Med Clin N Am., 78:225-245 (1994)
		Lavie, Letter to Editor, JAMA 1994; 272:513-515
		Keenan, Letter to Editor, JAMA 1994; 272:513-515
		Shields & Beckmann, Letter to Editor, JAMA 1994; 272:513-515
		Thomas N. Tozer, <i>Clinical Pharmacokinetics Concepts and Applications</i> (3d ed. 1995) at Chapter 9, p. 120
		Excerpts from the 1995 United States Pharmacopeia (pp. iii-vi, 1080-1082, 1793-1799, 1940-1944)
		Morgan & Capuzzi Abstract, <i>Safe and Effective Treatment of Dyslipidemia by Niaspan, a New Sustained-Release Niacin</i>, Clinical Pharmacology & Therapeutics (February 1996)
		Morgan & Capuzzi Article, <i>Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial</i>, J. Cardiovasc. Pharmacol. Therapeut. 1(3):195-202 (July 1996)
EXAMINER	<i>L. Channarayana</i>	DATE CONSIDERED <i>12/29/05</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
 Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/960,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		APPLICANT Eugenio Cefali, et al.	
		<div style="text-align: center;"> RECEIVED JAN 04 2005 </div>	
LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		FILING DATE 31 October 1997	GROUP 1615
OTHER DOCUMENT(S) (Including Author, Title, Date, Periodical, Pages, etc.)			
A		Capuzzi DM, et al., Efficacy and Safety of An Extended-Release Niaspan (Niaspan): A Long-Term Study, Am J Cardiol. 1998;82:74U-81U	
		Guyton JR, Advances in Dyslipidemia: Discussion Session II, Am J Cardiol, 1998: 82(12A): 85U-86U	
		Knopp RH, et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 47:1097-1104 (1998)	
		American Diabetes Association: Management of Dyslipidemia in Adults with Diabetes, Diabetes Care 21:179-182, 1998	
		Elam MB, et al., Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients With Diabetes and Peripheral Arterial Disease, JAMA: 2000; 284:1263-1270	
		Kesala R, et al., Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP), Diabetes 49 (suppl. 1): A268 at 1114-P (June 2000)	
		2001 NCEP Report at VI-11, Table VI.2-3	
		Wang, W. et al., Effect of Nicotinic Acid Administration on Hepatic Very Low Density Lipoprotein-Triglyceride Production, Am J Physiol Endocrinol Metab., 280:E540-E547 (2001)	
		Smith SC, et al., AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients with Atherosclerotic Cardiovascular Disease: 2001 Update. AHA/ACC Scientific Statement, 1577-79	
V		Tavintharan S and Kashyap M, The Benefits of Niacin in Atherosclerosis, Curr Athero. Reports 2001; 3:74-82	
EXAMINER <i>L. Channarayana</i>		DATE CONSIDERED <i>12/29/05</i>	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO 1449 (modified)		ATTY DOCKET NO. 5045-56103USCIP	APPLICATION NO. 08/860,577
U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary)		APPLICANT Eugenio Cefali, et al.	
		<div style="text-align: right; font-weight: bold; font-size: 1.2em;">RECEIVED</div> <div style="display: flex; justify-content: space-between;"> FILING DATE 31 October 1997 JAN 04 2005 GROUP 1615 </div>	
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)			
R		Meadows M., <i>Serious Liver Injury: Leading Reason for Drug Removals, Restrictions</i> , FDA Consumer Magazine, May-June 2001; http://www.fda.gov/fdac/features/2001/301_liver.html	
		Grundy SM, et al., <i>Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated with Type 2 Diabetes</i> . Arch Intern Med. 2002; 162: 1568-1576	
		American Diabetes Association: <i>Management of Dyslipidemia in Adults with Diabetes</i> , Diabetes Care 25:S74-S77, 2002	
		Pan J, et al., <i>Niacin Treatment of the Atherogenic Lipid Profile and Lp(a) in Diabetes, Diabetes, Obesity and Metabolism</i> 4:255-261 (2002)	
		Pan J, et al., <i>Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes</i> , Metabolism 51:1120-1127 (2002)	
		Meyers CD, et al., <i>Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia</i> , Ann Intern Med. 2003; 139:996-1002	
		CDER Guidance for Industry, <i>Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations</i> (March 2003)	
V		American Diabetes Association: <i>Dyslipidemia Management in Adults with Diabetes</i> , Diabetes Care 27:S68-S71, 2004	
EXAMINER		DATE CONSIDERED	
L. Channarayana		12/29/05	

Form #62

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 6 of 6